

Remarks/Arguments

Applicants have received and carefully reviewed the Office Action of the Examiner mailed October 8, 2008. Currently, claims 21-35 remain pending. Claims 21-35 have been rejected. Favorable consideration of the following remarks is respectfully requested.

Claim Rejections – 35 USC § 103

Claims 21, 22, and 24-31 were rejected under 35 U.S.C. 103(a) as being unpatentable over Engleson et al. (U.S. Patent No. 5,972,019), hereinafter Engleson, in view of Ginsburg (U.S. Patent No. 5,011,488). After careful review, Applicant must respectfully traverse this rejection.

“All words in a claim must be considered in judging the patentability of that claim against the prior art.” *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). (MPEP § 2143.03). As discussed previously and repeatedly acknowledged by the Examiner, nowhere does Engleson appear to disclose a cage assembly comprising both a proximal cage and a distal cage analogous to the proximal and distal cages of independent claims 21 and 26. Instead, Engleson appears to discuss a distal filter. Furthermore, nowhere does Ginsburg disclose proximal and distal cages. The Examiner has characterized Ginsburg as disclosing the use of a proximal and distal element (balloon). The Examiner then shifts terminology without justification and characterizes both the conical expandable tip (30) of flexible tube (14) and the inflatable body (16) of Ginsburg as teaching “the use of two cages”. Nowhere does Ginsburg use the terms “cage”, “frame”, “strut”, or the like which might serve to describe a cage or cage-like structure. The Examiner then continues to assert “Since Ginsburg teaches the use of two cages it is inherent that the proximal and distal cages would be able to be expanded by the same actuator element as shown above.” Applicants respectfully disagree with this position. The inherency, or lack thereof, depends both on having two cages, not taught or suggested by Ginsburg, and upon details of other portions of the structure which Ginsburg does not teach. The device of Ginsburg appears to provide a conical expansion

tip (30) at the distal end of an inner catheter (14), said catheter disposed about a third catheter, the flexible member (18). The third catheter, flexible member (18), is not attached to inner catheter (14) and the operation of Ginsburg appears to require that the expandable body (16) not be attached to, or deployed simultaneously with, the expansion tip. The expansion tip is a sole element at the distal end of a catheter and the expandable body is a sole body at the distal end of a separate catheter. Therefore there appears to be no basis for either the proposition that Ginsburg teaches a cage assembly having a proximal cage and a distal cage or for the proposition that the sequential deployment of the physically separate expanded catheter tip and balloon catheter by separate mechanisms, one relying on inflation and one mechanical, (See col. 6, lines 48-63 for the sequence.) renders the simultaneous deployment of two hypothetical cage structures, not found in Engleson, by a single activation mechanism, in any way inherent.

In arguing that Ginsburg teaches that an independent funnel-like expandable catheter end and a balloon teaches two linked cages, the Examiner appears to repeat the earlier assertion that a balloon would be understood to be equivalent to a cage which ignores the functional characteristics of a balloon and a cage (the latter is an open walled structure and the former is not) as reflected in the definitions of those terms as well as by the functional definition of the distal filter cage:

(Source: The American Heritage® Dictionary of the English Language)
 Cage NOUN:1. A structure for confining birds or animals, enclosed on at least one side by a grating of wires or bars that lets in air and light. 3. An enclosing openwork structure.

Balloon NOUN:1a. A flexible bag designed to be inflated with hot air or with a gas, such as helium, that is lighter than the surrounding air, causing it to rise and float in the atmosphere. 3. *Medicine* A sac that is inserted into a body cavity or tube and distended with air or gas for therapeutic purposes, such as angioplasty.

filter NOUN:1a. A porous material through which a liquid or gas is passed in order to separate the fluid from suspended particulate matter.

Were one of ordinary skill in the art to consider replacing the cage of Engleson by the balloon of Ginsburg, he or she would quickly discard that option because the balloon of Ginsburg is occlusive and would tend to deprive the brain, or other tissue distal of the device, of oxygen in a potentially lethal manner. Similarly, were one of ordinary skill in the art to consider replacing the flow-through cage of Engleson by the conical expanded tip of Ginsburg, he or she would have quickly discarded that option for the reason that critical blood flow would have been blocked during the procedure, particularly as the thrombus or clot is urged into the expanded tip by the occlusive balloon as seen in Fig. 5D, and the device would have been understood to be unsuitable treatment of a blocked vessel in the brain. (MPEP 2143.01, V.) See Figures 5C-5D for an illustration of the occlusive nature of both elements of Ginsburg. For at least the reason that Engleson does not teach or disclose a cage assembly including a proximal cage and a distal cage, said cage assembly actuatable from a first deployment shape to a second expanded shape by a common actuator and that Ginsburg also fails to teach or disclose a cage assembly including a proximal cage and a distal cage, said cage assembly actuatable from a first deployment shape to a second expanded shape by a common actuator, Engleson in view of Ginsburg does not appear to teach all the claim limitations, as is required to establish a *prima facie* case of obviousness.

In addition to not providing all of the elements of the pending claims 21 and 26, the Examiner has failed to provide a motivation for one of ordinary skill in the art to combine elements which exist in the two references. Further, the combination proposed by the Examiner appears to require an alteration of the operating principles of at least one of Engleson or Ginsburg which provides an indicia of unobviousness. (MPEP 2143.01, VI.) Either the expanded tip and balloon of Ginsburg fail to provide the filtering action required by the operation of Engleson because they prevent the passage of blood therethrough or the single porous filter of Engleson fails to allow aspiration of the thrombus and/or to draw the thrombus into the inner tube of Ginsburg without unduly shedding debris. Accordingly, Engleson in view of Ginsburg appear to fail the *Graham* inquiry and Applicants respectfully request that the rejections of claims 21 and 26 be withdrawn.

“the *Graham* factors, including secondary considerations when present, are the controlling inquiries in any obviousness analysis. The *Graham* factors were reaffirmed and relied upon by the Supreme Court in its consideration and determination of obviousness in the fact situation presented in *KSR*, 550 U.S. at ___, 82 USPQ2d at 1391 (2007).” (MPEP 2141, II.)

The Examiner has also rejected claims 21-31 under 35 U.S.C. 103(a) as being unpatentable over Schmaltz et al. (U.S. Patent No. 5,449,372), hereinafter Schmaltz, in view of Ginsburg (U.S. Patent No. 5,011,488) further in view of Crittendon et al. (U.S. Patent No. 4,719,924), hereinafter Crittendon. After careful review, Applicant must respectfully traverse this rejection.

As in the rejection over Engleson in view of Ginsburg, the Examiner expressly acknowledges that Schmaltz does not disclose a cage assembly including a proximal cage and a distal cage and attempts to replace the cage assembly with the conical expansion tip (30) at the distal end of an inner catheter (14), said catheter disposed about a third catheter, the flexible member (18). The third catheter, flexible member (18), is not attached to inner catheter (14) and the operation of Ginsburg appears to require that the expandable body (16) not be attached to, or deployed simultaneously with, the expansion tip of the inner catheter. Therefore there appears to be no basis for the proposition that Ginsburg teaches a cage assembly having a proximal cage and a distal cage, much less an actuator element common to both cages or that a combination of Schmaltz and Ginsburg would have either the elements or an alternate structure which inherently would allow one of ordinary skill in the art to appreciate that elements on two separate catheters, which must be capable of relative displacement in order to function as described, would be actuated by a common actuator. Immediately after discussing Schmaltz in view of Ginsburg, the Examiner acknowledged that the combination of Schmaltz and Ginsburg does not disclose “a core wire or guidewire having a coil tip and a cage assembly including a proximal cage and a distal cage.” Since Schmaltz does appear to have a coil tipped guidewire (92,94,130) and further because a coil tipped guidewire is not an element of independent claims 21 and 26 which were being rejected over Schmaltz in view of Ginsburg and Crittendon, the Examiner must have been acknowledging that the combination of the wire coil stent of Schmaltz and the two catheter, expanded tip and

balloon system of Ginsburg does not teach or otherwise disclose a cage assembly including a proximal cage and a distal cage for reasons similar to those advanced by the Applicants in discussing the wire coil filter of Engleson in view of Ginsburg. Crittendon appears to have been supplied solely for the purpose of supplying the core wire said to be missing from the combination of Schmaltz in view of Ginsburg and fails to overcome deficiencies of Schmaltz in view of Ginsburg. As in the case of Engleson in view of Ginsburg, the combination of references proposed by the Examiner, Schmaltz in view of Ginsburg and Crittendon fails to provide the claimed elements of the invention and does not appear to be capable of motivating one of ordinary skill in the art at the time that the invention was made to combine the elements present in the three references, much less to combine them in a manner which would result in the invention of claims 21 and 26. Accordingly, Applicants respectfully request that the rejections of claims 21 and 26 be withdrawn.

Additionally, for similar reasons, as well as others, claims 22-25 and 27-35, which depend from claims 21 and 26 respectively and include significant additional limitations thereto, are believed to be patentable over Schmaltz in view of Ginsburg and Crittendon and Applicants respectfully request withdrawal of the rejections.

If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988). (MPEP 2143.03)

In the Examiner's Response to Arguments, the Examiner attempts to return to the discredited propositions that a) Ginsburg teaches first and second cages and that the first and second cages are on a common elongated core wire; b) that were one to provide two cages, for some undisclosed reason necessarily unrelated to the teachings of either Engleson, Ginsburg, or a combination thereof, that a single actuator would inherently actuate the two cages corresponding to a mechanically expandable tip on one catheter and an inflatable balloon on a different catheter unconnected to the first, said elements being actuated in Ginsburg by separate means at separate times; and c) an improper characterization and application of *St. Regis Paper v. Bemis Co.*, 193 USPQ8. A pre-

appeal brief based largely upon the proper application of *St. Regis Paper* resulted in withdrawal of the rejections and their absence from the subsequent Office Action.

Engleson has been acknowledged by the Examiner to not teach a plurality of cages. Ginsburg has been acknowledged by the Examiner to not teach a plurality of cages, the balloon of Ginsburg does not replicate the expandable tip of Ginsburg. The expandable tip of Ginsburg does not share an actuation method with the balloon of Ginsburg. Engleson does not have a second cage which could share an actuation method with a first cage of a gage assembly. With respect to the assertion that the first and second cages of the cage assembly of pending claims 21 and 26 are mere duplication of parts of a device, the Examiner's attention is directed to the fact that the function and, more generally, the structure of the two cages are significantly different. That the structures are not the result of mere duplication may be seen clearly in Figure 3A and by comparing the proximal displacing cages of Figs. 2A and 3A with the distal filter cages of Figs 3A, and 4A and 4B. The differentiated functions performed by the proximal and distal cages, and thus their differentiated structures are illustrated in Fig. 6D. The first cage is characterized throughout the application as a proximal displacing cage while the second cage is a distal filter. The claims do not limit the proximal and distal structures of the claimed cage assembly to identical cages and so do not involve mere duplication. The differences between the distal and proximal cages are explicitly described in the dependent claims.

In view of the foregoing, all pending claims are believed to be in a condition for allowance. Reexamination and reconsideration are respectfully requested. Issuance of a Notice of Allowance in due course is anticipated. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

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